GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

1010 WISCONSIN AVE., NW
NINTH FLOOR
WASHINGTON, DC 20007
PHONE (202) 337-9400
FAX (202) 337-4508
www.gmabrands.com

May 18, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Docket Management Branch Manager:

Attached please find the Grocery Manufacturers of America's (GMA) comments to [Docket No. 98N-1038] Irradiation in the Production, Processing, and Handling of Food, per the request of the Department of Health and Human Services. Request for comments appeared in volume 64 of the Federal Register, page 7834 (February 17, 1999). We appreciate this opportunity to comment.

Sincerely,

Stacey A. Zawel, Ph.D.
Vice President, Scientific & Regulatory Policy

Enclosure

98N-1038

C1956

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

1010 WISCONSIN AVE., NW
NINTH FLOOR
WASHINGTON, DC 20007
PHONE (202) 337-9400
FAX (202) 337-4508
www.gmabrands.com

May 18, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
Parklawn Building
5630 Fishers Lane
Rockville, MD 20852

Re: Irradiation in the Production, Processing, and Handling of Food
Docket No. 98N-1038
64 Fed. Reg. 7834 (February 17, 1999)

We submit these comments on behalf of the Grocery Manufacturers of America (GMA). GMA is the world's largest association of food, beverage and consumer product companies, with 176 members and numerous associate members worldwide. GMA's member companies employ more than 2.5 million individuals in all 50 states and are responsible for United States sales of more than $450 million.

Executive Summary

The purpose of the current advance notice of proposed rulemaking (ANPR) is not to decide whether food irradiation is safe, but whether to communicate to consumers the fact that irradiation has been used to make the food they purchase safer. The ANPR evidences specific and, GMA believes, well-founded questions about consumer understanding of food irradiation and about the way in which current labeling practices inhibit that understanding.

GMA believes that current irradiation labels look like warnings and therefore discourage consumers from purchasing irradiated foods. If consumers will not buy irradiated foods, food producers will not sell them. In other words, FDA's current labeling for irradiated foods discourages the use of a technology that could deliver safer and better quality food to consumers.

GMA believes that irradiation is a process and that the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not provide for the disclosure of food processing methods on food labeling. If FDA nonetheless continues to require irradiation disclosure, FDA should revise the labeling requirements to ensure that the label does what it is supposed to do: provide the consumer with sufficient information to make an informed choice.

I. Background

A. Irradiation Protects the Food Supply

Food irradiation, sometimes called "cold pasteurization," is the process of exposing food to limited amounts of radiant energy, such as high voltage electrons, gamma rays, or x-rays. The process kills insects, parasites, and bacteria that cause serious foodborne illnesses in humans (including e.coli, listeria, campylobacter, and certain species of salmonella). Irradiation also prolongs the shelf life of products.

Because irradiation does not substantially raise the temperature of the food being processed, nutrient losses are small and chemical changes in the irradiated food are minimal.

B. The International Community's Approval of Food Irradiation

FDA and numerous other national and international organizations have been studying food irradiation for the last 50 years and have concluded that irradiated foods are safe for human consumption. Over time, FDA has approved the use of irradiation for a growing list of foods and food ingredients, including: wheat, potatoes, spices, poultry, and refrigerated or frozen uncooked red meat. In May 1997, the European Community issued directives authorizing the use of ionizing radiation for dried aromatic herbs, spices, and vegetable seasonings.

Numerous international health organizations have endorsed food irradiation, among them: the World Health Organization; the International Atomic Energy Agency; the United Nations Joint Expert Committee on Wholesomeness of Irradiated Food; the Codex Alimentarius Commission; the American Medical Association; the American Gastroenterological Association; the United Nations Food and Agriculture Organization; the American Dietetic Association; and the United States Center for Disease Control and Prevention. Approximately forty other countries use food irradiation to protect their food supplies.

Notwithstanding the decades of research on food irradiation and the acceptance by national and international organizations dedicated to the preservation of public health, consumers remain confused about whether food irradiation is safe. This is borne out by a survey of consumer attitudes towards food irradiation that was conducted for GMA in 1998.

C. Consumer Attitudes Towards Irradiation: The GMA Survey

GMA retained Peter D. Hart Research Associates to conduct a nationwide telephone survey among a representative sample of 1002 primary grocery shoppers.[1] The Hart Survey found that "nearly half (48%) of shoppers favor the use of irradiation to increase the safety of some foods -- including meat, poultry, and produce -- by killing germs and bacteria,

---

[1] *Opinion '98: Consumers Speak Out on National Brands, Eating Habits and Food Irradiation,* Survey Conducted for the Grocery Manufacturers of America by Peter D. Hart Research Associates, Inc. (May 1998)(the "Hart survey"). The margin of error is +/- 3.2%. The report is available on GMA's website at http://www.gmabrands.com/opinion98/intro.htm.

while 26% oppose using this process. . . .fully one in four (26%) shoppers are undecided about it."[2] The Hart Survey found that shoppers assumed that irradiation would have an adverse effect on the taste and cooking of foods: "[a]lthough consumers are less concerned about the result of irradiation on taste and preparation, . . .more than one-third think that it will have a negative effect on taste and more than one-fourth believe that it will hurt the preparation and cooking of foods."[3]

When asked what information would be helpful to them in making a decision about food irradiation, the shoppers surveyed requested information about the health effects of irradiated foods on humans (56 percent), the amount of research that has been conducted concerning food irradiation (36 percent), and the effect of food irradiation on the nutritional content of the irradiated food (22 percent).[4] GMA and others in the food industry are making a concerted effort to educate consumers about the benefits of irradiation. But, as the GMA survey and the other consumer surveys discussed below indicate, consumers are not well informed about irradiation.

II. Current Labeling Contributes to Consumer Confusion

GMA believes that flaws in FDA's current approach to the labeling of irradiated food contribute to consumer confusion about the safety of such food products.

The FD&C Act does not state that food processing techniques – as distinguished from ingredients – must be listed on food labels. Numerous other forms of safe food processing are used without any form of special labeling. Thus, the irradiation labeling requirements conflict directly with both the FD&C Act and FDA policy concerning the declaration of safe methods of food production and processing. For example, when FDA approved the use of the bovine growth hormone, BST, to promote the production of milk, FDA explicitly decided against special labeling requirements for milk produced from animals to whom BST was administered because FDA found that BST was safe and there was "no significant difference" between milk from treated and untreated cows.[5] When Vermont subsequently required such special labeling, the Vermont law was held unconstitutional because it had no public health basis.[6]

The same logic should apply to irradiated foods. Paradoxically, FDA concluded that irradiation is safe when used as provided in the irradiation regulations, and yet required

---

2 Hart Survey at 2. See also Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4. Colum. J. Eur. L. 525, 529 (Summer 1998)("[I]n the U.S. most consumers do not vigorously oppose irradiation and modern generic engineering.").

3 Hart Survey at 5.

4 Hart Survey at 5.

5 59 Fed. Reg. 6279, 6280 (February 10, 1994).

6 International Dairy Foods Ass'n v. Amestoy, 92 F.3d. 67, 73 (2d Cir. 1996).

labeling disclosures that now inhibit the use of irradiation. FDA clearly explained that the irradiation disclosures were not prompted by safety concerns, but were intended to avoid consumer confusion as to whether the product had undergone processing.[7] GMA believes that singling out irradiation for special labeling suggests to the consumer that irradiation is not safe. In addition, GMA is concerned that placing irradiation information on a food label in the same way as ingredients are listed misleadingly suggests to consumers that the food contains radiation.

With that as background, we address the questions posed by FDA in the ANPR. The specific questions addressed are shown below in italics.

III. GMA's Answers to Certain Questions Posed by FDA

Most of the questions posed by FDA presume some level of consumer familiarity with the radura logo and irradiation labeling as well as with the purpose and methods of food irradiation. Our research indicates that understanding of these matters is not widespread in the consumer population. In March 1998, GMA -- together with the Food Marketing Institute, the National Restaurant Association and the American Meat Institute -- commissioned a survey of consumer opinions concerning irradiation. The results of this survey were published in a report called Consumers' Views on Food Irradiation (FMI 1998)(Consumer Survey) from which we quote extensively because it specifically addressed many of the questions raised in the ANPR.

Survey participants were given the following explanation of irradiation:

> Irradiation is a process to preserve or sterilize food. It has been approved by the U.S. Food and Drug Administration as a way to make food safer from certain harmful bacteria and slow down spoilage.... It basically exposes food to energy in the form of gamma rays, X-rays or electrons and does not make the food radioactive. Most commonly used are gamma rays. Gamma rays are very short wavelengths similar to ultraviolet light and microwaves. They penetrate the food and its packaging, but more of the energy simply passes through the food, similar to the way microwaves pass through food, leaving no residue.[8]

A. The Current Irradiation Disclosure Statement

1. Does the current radiation disclosure statement convey meaningful information to consumers in a truthful and nonmisleading manner?

As noted above, GMA believes that, by listing the process of irradiation on a label in much the same way that ingredients are listed, the irradiation legend suggests to consumers

---

7 51 Fed. Reg. 13376, 13388 (April 18, 1986).

8 Consumer Survey at 7.

that the irradiated product "contains" radiation or is radioactive. Thus, the labeling is severely misleading. In addition, the current irradiation legend does nothing to indicate that irradiation makes the food safer for human consumption -- a fact which is even more material to the consumer than the fact that the food has been irradiated.

The use of the term "irradiation" without explanation alarms consumers. To some, the term carries "images of atomic explosions or nuclear reactor accidents."[9] Misleading advertisements used by anti-irradiation advocacy groups exacerbate these fears. In sum, GMA believes that current labeling is too cryptic to be useful to a consumer, particularly when that consumer is confronted with anti-irradiation advocacy.

B. Alternate Irradiation Disclosures

2. What specific alternate wording for a radiation disclosure statement would convey meaningful information to consumers, in a truthful and nonmisleading manner, and in a more accurate or less threatening way than the current wording?

The wording of current and alternative radiation disclosure statements was a major focus of the survey discussed in the Consumer Survey, which had these comments about alternative wordings:

> Consumers have mixed opinions about the term "irradiation." Half are comfortable with the word being used to describe the process, while the other half are not. Related terms such as "cold pasteurization" or "electronic pasteurization," have only slightly more appeal, with 56 percent and 55 percent, respectively, saying they are comfortable with those terms. Consumers under age 55 and/or with household incomes of $40,000 or more, are more likely than other groups to feel comfortable with "cold pasteurization" as a term.
>
> Other terms have even less appeal – only three in 10 consumers are comfortable with the terms "treated with gamma rays" and "ionizing radiation."[10]

The following table sets forth the general reactions of the consumers surveyed to certain terms:

---

[9] *Irradiation: A Safe Measure for Safer Food*, 32 FDA Consumer 12, 16 (May-June 1998).

[10] Consumer Survey at 25. The Consumer Survey also noted that there is considerable debate within the food industry over the use of the term "cold pasteurization" because "[p]roponents say 'cold pasteurization' could be used because irradiation kills pathogens without raising the product's temperature the way regular heat pasteurization does. Others, however, believe that 'cold pasteurization' is misleading, because irradiation and pasteurization are entirely different processes." Id. at 27.

Term	Responses (in percentages)	
	Comfortable	Not Comfortable
Cold Pasteurization	55.9	40.2
Treated with Gamma Rays	31.6	65.2
Ionizing Radiation	31.3	65.2
Electronic Pasteurization	54.6	42.3
Irradiation	49.8	48.6

Source: Consumer Survey at 42-44[11]

In early 1998, the International Food Information Council (IFIC) commissioned Axiom Research Company to conduct a series of consumer focus groups, which also considered alternate descriptions of the irradiation process. The IFIC Report explained:

> By far, "cold pasteurization" was the most popular of a series of names tested to describe the process. To most consumers, cold pasteurization evoked a familiar process, "updated for the 90s." Consumers agreed that this name should be followed by "irradiation" in parentheses which would provide consumers with the name of the process (irradiation) along with a definition (cold pasteurization). This refinement of the name satisfied even the most skeptical consumers. Other names evaluated were viewed negatively, including: "electronic pasteurization," "energy pasteurization," and to a lesser extent "ionization."[12]

GMA believes that it is also important to explain to consumers what irradiation does. This view is supported by consumer research. For example, the Consumer Survey also asked respondents whether they would buy a food labeled "irradiated to kill harmful bacteria." 31.9% of the respondents said they would be "very likely" to buy such foods; 47.6% said "somewhat likely," and 19.5% said "not likely."[13] Notably, the percentage of consumers "very

---

[11] Percentages do not reflect margins of error, or other responses, including "doesn't matter to me." "don't care" "don't know" or "no answer."

[12] Consumer Attitudes Toward Food Irradiation: Analytical Report of Focus Groups Conducted for International Food Information Council (Axiom Research Company July 1998) 4 (IFIC Report).

[13] Consumer Survey at 45. These figures do not account for statistical margins of error, which are discussed elsewhere in the Consumer Survey.

likely" to buy foods labeled in this manner jumped to 37.5% when the foods were being purchased for consumption by children.[14] Similarly, the IFIC Report commented that "[c]old pasteurized (irradiated) to eliminate harmful bacteria" "[i]rradiated for your safety," and "[t]reated with irradiation to eliminate harmful bacteria" were perceived to be the most informative and important of the legends that might accompany the radura logo.[15]

C. Consumer Experience With and Understanding of the Irradiation Process

5. *What is the level of direct consumer experience with irradiated foods that are labeled as such?*

6. *What do consumers understand to be the effect of irradiation on food? For example, what do consumers understand about the effect of irradiation on the numbers of harmful microorganisms in or on food?*

It is fair to say that most American consumers have little direct experience with irradiated foods that are labeled as such. It stands to reason that consumers are unlikely to become familiar with irradiated foods when there is a limited number of irradiated foods on the market for them to buy. That is the case in the United States. For example, last month, the Minneapolis Star Tribune reported that no supermarket in the state of Minnesota carries irradiated products.[16] In fact, the Consumer Survey noted that one facility -- Food Technology Service Inc. in Mulberry, Fla. -- is responsible for the preparation of most irradiated foods in the United States. Food Technology was the first commercial irradiator in the United States. It began its operations in 1992, less than 10 years ago.

In light of this lack of experience, it is not surprising that consumers consistently express a need for additional information about irradiated foods in order to decide whether to purchase them. The Consumer Survey found that consumers were particularly concerned about how effective irradiation is in controlling bacteria:

> Just over 60 percent of all consumers say irradiation's effect on both harmful bacteria and nutrition is "very important" to know about. Only 47 percent say taste is very important, and only 37 percent think the extension of a food's shelf life is that important.[17]

---

14 Consumer Survey at 45.

15 IFIC Report at 6.

16 Jill Burcum, *A bug-zapper for food; Many health experts say irradiation is not only safe but needed,* Minneapolis Star Tribune 14A (April 7, 1999).

17 Consumer Survey at 9.

Surveys conducted by the University of California at Davis, the University of Georgia, and Indiana University yielded the same conclusions: "When you ask people if they would ever buy irradiated food, 50 to 60 percent say they would.... When you mention that irradiation can keep food fresh longer and kill bacteria, the percentage rises to 80."[18]

The IFIC Report also concluded that consumers wanted a "clear and direct" explanation of the benefits of radiation. Consumers preferred the phrase "to eliminate harmful bacteria" to the vaguer "health benefits."[19] They preferred that the explanation contain the words "harmful bacteria/germs" rather than "foodborne pathogen."[20]

The Consumer Survey also showed that the source of information concerning irradiated foods was important to consumers. The survey reported that "[c]onsumers. . .are most likely to trust health and medical professionals for information about irradiation, followed by university experts. These groups are trusted more than the food industry, the media, or government."[21]

D. The Radura Logo

8. Do consumers understand the logo to mean that a food has been irradiated?

9. Do consumers perceive the radura logo as information, as a warning, or as something else?

The IFIC focus groups mentioned above considered the impact of the radura logo and concluded that "the radura alone was insufficient to identify irradiated foods."[22] The IFIC Report added:

> The Radura symbol was considered appealing and pleasant, and elicited a very positive reaction among nearly all consumers. Most consumers agreed though that this symbol would be too misleading or vague to stand alone on a product, as an uninformed individual might think it was a brand. Still, a number of participants said they would be inclined to buy irradiated foods if they saw this label.[23]

---

18 Skerret at 35 (quoting Christine Bruhn, director of the Center for Consumer Research at the University of California at Davis).

19 IFIC Report at 5.

20 IFIC Report at 5.

21 Consumer Survey at 28.

22 Consumer Survey at 27.

23 IFIC Report at 6 (underscore added).

It bears mention that no other country in which irradiated foods are marketed uses the radura symbol alone without an accompanying legend to indicate that the food product has been irradiated.[24] If the process is identified, there is no need or justification for the radura logo as well.

E. Expiration of Irradiation Labeling Disclosures

11. Should any requirement for a radiation disclosure statement expire at a specified date in the future?

12. If so, on what criteria should the expiration be based?

13. If the expiration of labeling requirements for irradiated foods is to be based on consumer familiarity with the radura logo and understanding of its meaning, what evidence of familiarity and understanding would be sufficient to allow these requirements to expire?

The consumer research to date clearly demonstrates that consumers are neither familiar nor comfortable with the irradiation disclosure or the radura logo. GMA believes that consumer education programs now being undertaken by GMA and others in the food industry, together with more increased availability of irradiated foods, are the keys to widespread consumer acceptance of irradiation. This in turn will yield greater protection of public health.

GMA opposes the continued use of irradiation labeling of any kind. If it is to be retained, GMA proposes that FDA adopt a three-year sunset provision for any amended labeling, coupled with intensified consumer education by the food industry and FDA. In addition, we strongly recommend that any amended labeling apply only to retail packaged products that have been irradiated, not to foods containing irradiated ingredients.

IV. Conclusion

Food irradiation and food labeling have a common purpose: to protect the consumer. GMA believes that the current labeling chosen by FDA does not enable consumers to make an informed choice with respect to irradiated food. Because the radura symbol is ambiguous and the word reference to "irradiation" is not well understood by consumers, these labeling components appear to be warnings rather than to convey helpful safety information. To do that, the labeling should inform consumers that the food has been irradiated to make the food safer for human consumption. GMA does not believe that any form of irradiation labeling is compelled by governing law or by FDA's past practices and urges FDA to withdraw this labeling. If FDA does continue to require irradiation labeling, GMA strongly advocates the use

---

[24] *A Roundtable on Food Irradiation: Identifying, Addressing and Overcoming Consumer Concerns,* 7 World Food Regulation Review 23, 29 (1998).

of the "cold pasteurized (irradiated) to make food safer from harmful bacteria" or similar legend for a limited period of approximately three years.

Stacey A. Zawel, Ph.D.
Director, Scientific and Regulatory Affairs

James H. Skiles
Vice President and General Counsel

GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

1010 WISCONSIN AVE., NW
NINTH FLOOR
WASHINGTON, DC 20007

Hand Delivered By *(202) 338-0930*

Apple Courier Incorporated

L

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852